## REMARKS

The Office Action of January 25, 2006, has been carefully reviewed, and in view of the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

In the above Office Action, claim 1 was rejected under 35 U.S.C. § 112, first and second paragraphs; claims 1, 2, 5, 6, 11-13, 15 and 19 were rejected under 35 U.S.C. § 103(a) as unpatentable over *Houston et al.* (U.S. Patent No. 5,894,014) in view of *Spence* (U.S. Patent No. 4,919,888); claims 3, 4, 7-9 and 16-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Houston et al.* in view of *Spence* and further in view of *Quehl* (U.S. Patent No. 4,165,404). Claim 10 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over *Houston et al.* in view of *Spence* and *Quehl* and further in view of *Leimbacher et al.* (U.S. Patent No. 5,837,181).

With regard to the rejection under Section 112, first paragraph, the Examiner's attention is directed to page 3, lines 31-34, indicating that the chamber is releasably mountable in the sterilization device so that it is an easily exchangeable component. That is, referring to page 6, line 35 – page 7, line 2, it may be removed from the sterilization device and replace. Further, page 4, lines 8-10, indicate that the inlets and outlets for steam, moist and the like are integrally formed with the chamber. Hence, if the chamber is releasably mounted and the inlets are integral with the chamber, it stands clearly that the inlet connection to the sterilant source is also releasable so as to allow removal of the chamber. Accordingly, Applicants submit the feature is adequately described for one skilled in the art. However, in an effort to expedite prosecution, Applicants would be wiling to remove the feature of a

releasable connection to the sterilant source if required by the Examiner to secure allowance of the present case.

With regard to the rejection under Section 112, second paragraph, the Examiner's attention is directed to page 5, lines 8-11, indicating that the sterilization device includes pressure means and vaporization means in accordance with prior art devices. Page 6, lines 16-18, further indicates that the sterilization process occurs when vapor, water, and so on is fed into the chamber in a per se known manner. Hence, Applicants submit that pressure means as used in the field of sterilization devices are known in the field and would not render claim 1 indefinite when read by one skilled in the art.

In view of the above, Applicants submit the rejections under Section 112 must be withdrawn.

Claim 1 as set forth above is directed to a sterilisation chamber for use in a sterilisation device. The sterilisation chamber is releasably fastened within the sterilization device by releasably connecting the front portion and the rear portion to the housing of the sterilisation device. An interior of the sterilisation chamber is pressurized during the sterilisation process so as to define a sealed pressure chamber and the sterilisation chamber comprises a self-supported structure being essentially manufactured from a polymeric material.

The primary reference upon which the Examiner relies, *Houston*, is directed to a sterilization device 10 comprising a sterilization chamber 12 surrounded by a jacket 14. Steam enters the chamber 12 through an inlet 16 and exits the jacket 14 through an outlet 18. The chamber is secured to upper frame element 28. The sterilization

device 10 further includes a front panel 60 fixed thereto which provides user controls and access to the chamber interior.

The Examiner contends that the chamber 12 of *Houston* is releasably fastened within the sterilization device by the unlabeled fasteners in frames 20 and 22 in Figure 1 connecting the front portion and the rear portion of the chamber 12 to the housing. Applicant respectfully disagrees. The vertical frames 20 and 22 are connected to upper frame element 28, which element 28 is **secured** to chamber 12 (col. 2, lines 60-61) (emphasis added). Hence, it is the bottom of the chamber that is fastened to the horizontal frame element 28, not the front and rear portions as recited in claim 1. Further, there is no disclosure that the chamber 12 is or is intended to be releasable from the unit 10. The sterilization unit 10 includes a front panel 60 which is **fixed** to the sterilization unit 10 to provide user controls 70 and access to the chamber interior. Referring to Figure 7, in conjunction with Figure 1, it is clear that the opening in the front panel 60 is not intended for release of the chamber 12 therethrough. Accordingly, Applicants contend that *Houston* fails to disclose or suggest releasable fastening of the chamber within the sterilization unit 10.

The Examiner recognizes that *Houston* fails to teach designing the chamber essentially from a polymeric material and relies upon *Spence* for this teaching. As the Examiner's position is best understood, Applicants concur that *Spence* does disclose the use of a polymeric material to form a container in certain limited conditions. These conditions, however, require that the container be used within a pressurized sterilization chamber. That is, the polymeric container disclosed in *Spence* is better known in the art as a sterilization cassette and it cannot function by

itself as a sterilization chamber (See, Declaration under 37 C.F.R. 1.132 of Johan Wanselin, filed March 30, 2005). In fact, as mentioned in *Spence* (and as a skilled person would interpret the description) the polymeric container/cassette must be inserted into a sterilization chamber, which chambers are previously known in the art and made of metal, such as stainless steel.

The Examiner refers to the following in *Spence* (col. 4, lines 30-33), asserting that the sterilization chamber "may be made of any suitable metal and/or plastic material which are not adversely affected by the sterilant or by the sterilization conditions." Applicants respectfully traverse the Examiner's reasoning in substituting the plastic container of *Spence* for an ASME-certified sterilization pressure chamber (i.e., one that is verified with extensive FEM-analysis). Thus, it is not the same pressure conditions for a *Spence* container with filter means being equalized in a sterilization pressure chamber and a sterilization pressure chamber (ASME-certified). See, the Declaration under 37 C.F.R. 1.132. The *Spence* container is not suitable to be used as a pressure chamber (internally pressurized), especially not according to the ASME. For instance, the container has only a microorganism proof seal between the lid and the base and is not adapted to be internally pressurized.

Thus, if modified as the Examiner suggests, there is no teaching or suggestion that the sterilization chamber of *Houston* would be able to withstand the sterilization pressures to be exerted thereon. The Federal Circuit has held that if a "proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). As such, Applicants submit that there is no motivation to combine

the teachings of *Spence* with the sterilization unit of *Houston* to make the modification proposed by the Examiner.

There are some major differences between the present invention and the cited documents, *Houston* and *Spence*. By using a plastic cassette instead of a cassette made of metal as mentioned in *Spence* (col. 4, line 30-33), the skilled person would be led in the opposite direction when comparing with the present invention. A plastic cassette (*Spence*) will actually make it more difficult to sterilize the object inside the cassette (hot exterior). For instance the present invention improves the sterilization process/properties, for instance by improved isolation properties (compared with *Houston* and *Spence*) but also the following

- cool exterior
- less noise
- lower consumption of energy
- shorter processing time
- achieve dry goods quicker
- reduce bacterial build up
- less condensation

Applicants further note that the cassette disclosed in *Spence* must be destroyed (the belts) when opened and a sterilization pressure vessel is generally adapted for 50,000 pressure cycles.

"Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." In re Dembiczak, 175 F.3d 994, 998 (Fed. Cir. 1999). This is because "[c]ombining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together

the prior art to defeat patentability—the essence of hindsight." Dembiczak, 175 F.3d at 999.

Thus, given the above-described differences between *Spence* and a true sterilization device, as in *Houston* and the claimed invention, Applicants submit there is no motivation to combine the same, without the insidious use of hindsight, and that the rejection of independent claim 1 must be withdrawn.

The remaining dependent claims are also patentable based at least upon their dependence on claim 1.

**CONCLUSION**

In view of the above amendments and remarks, Applicants respectfully submit that the claims of the present application are now in condition for allowance, and an early indication of the same is earnestly solicited.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference would be helpful in resolving any remaining issues pertaining to this application; the Examiner is kindly invited to call the undersigned counsel for Applicants regarding the same.

Respectfully submitted,

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